K061350
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510(k) SUMMARY

PCK's LithoDiamond ULTRA

DEC 2 2 2006

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Filing Date: May 15, 2006

Name of Device and Name/Address of Sponsor

Proprietary Device Name:	LithoDiamond ULTRA
Common/Generic Device Name:	Extracorporeal Shock Wave Lithotripter
Classification Name:	Lithotripter, extracorporeal shock-wave, urological

Product Code:	LNS
Regulatory Class:	Class II
Regulation Number:	21 CFR 876.5990
Sponsor	PCK Electronic Industry and Trade Company, LTD, Inc. 1 Organize Sanayi Bolgesi Orhan Isik Cad. No:4 Sincan 06935 Ankara TURKEY

Predicate Devices

The LithoDiamond ULTRA Extracorporeal Shock Wave Lithotripter is substantially equivalent to the following currently marketed devices:

- PCK Stonelith V5
- Dornier Compact Delta
- Siemens Lithostar Modularis
- Storz MODULITH Model SLX-F2
- United Medical Systems' Piezolith 300 Lithotripter

Intended Use / Indications for Use

The LithoDiamond ULTRA is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

Technological Characteristics

The LithoDiamond ULTRA consists of: (1) a Therapy Unit; and (2) a Control Interface Master.

The Therapy Unit consists of the following submodules: (a) shock wave generator with therapy head; (b) movement unit (patient table and X-ray Isocentric C-Arm; (c) X-ray Component; (d) optional Ultrasound Localization System ("ULS") and (e) accessories. The X-ray Component of the Therapy Unit consists of the following modules: (a) X-ray module (monoblock and collimator), where the X-rays are generated; (b) Imaging Module, where the X-ray Image is detected and processed; (c) Electronics Module, containing control modules and power supplies; and (d) one or two high resolution black and white monitors. The X-ray

Module and Imaging Module are mounted on a turnable C-Arm. The Electronics Module is mounted within the LithoDiamond ULTRA's Housing.

The Control Interface Master contains: (1) one or two X-ray Monitors; (2) the Control Panel; (3) the Remote Monitoring Connector Box; (4) the Release Buttons for X-ray and Shock Wave Generator; (5) the Foot Switch for the X-ray; and (6) a server PC accommodating the Software.

The LithoDiamond ULTRA is a modification to PCK's cleared Stonelith V5 device (K011106). The principal design changes to the Stonelith V5 lithotripter to form the LithoDiamond ULTRA lithoptriper are as follows: (1) use of interchangeable shock heads to provide electromagnetic and electrohydraulic therapy (in contrast to the existing StoneLith V5 device which delivers only electrohydraulic therapy); (2) replacement of the fixed imaging arm ("U" arm) (used with the Stonelith V5) with an Isocentric C-Arm; (3) changes in the software (used with the Stonelith V5) to accommodate the use of both electrohydraulic and electromagnetic therapy as well as the C-arm; (4) the addition of a motorized shock head; and (5) certain minor changes in the dimensions of the support table.

Performance Data

In accordance with FDA's Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Uretal Calculi (August 9, 2000), PCK conducted the following types of performance testing: Shock Wave Characteristics; Localization Accuracy; Road Testing; and Clinical Performance Testing. In all instances, the LithoDiamond ULTRA met its specifications and functioned as intended. The laboratory and clinical data provide reasonable assurance of the safety and effectiveness of the LithoDiamond ULTRA for the extracorporeal fragmentation of urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

Substantial Equivalence

The LithoDiamond ULTRA has the same or similar intended uses and indications for use; similar principles of operation; and similar technological characteristics as its predicate devices. The technological differences between the LithoDiamond ULTRA and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the LithoDiamond ULTRA is as safe and effective as the predicate devices. Thus, the LithoDiamond ULTRA is substantially equivalent to legally marketed extracorporeal shock wave lithotripters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

PCK Electronic Industry and Trade Company, LTD
c/o Jonathan S. Kahan
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WASHINGTON DC 20004

DEC 22 2006

Re: K063150
Trade/Device Name: LithoDiamond® ULTRA Extracorporeal Shock Wave Lithotripter
Regulation Number: 21 CFR §876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: LNS
Dated: October 25, 2006
Received: October 25, 2006

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: (K061350)

Device Name: LithoDiamond ULTRA

Indications for Use:

To fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

Prescription Use X AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061350

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